Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2026717	04/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Regional Laboratories Pathology	120 Ne 167th Street, North Miami Beach, FL	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey conducted from 04/18/2023 to 04/28/2023 found the INTEGRATED REGIONAL LABORATORIES PATHOLOGY clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory procedure manual failed to include the instruction for making the solution for alcohol 95% used for the Hematoxylin and Eosin stain. Findings included: -During the tour of the laboratory on 04/18/2023 at 11:30 AM, in the flammable cabinet there was one gallon container of

	Reagent Alcohol from Cardinal Health with lot # 122661. -Review of the Hematoxylin and Eosin (H&E) stain procedure revealed that the laboratory used alcohol 100% and 95%. -Review of the procedure manual revealed that the procedure failed to include the preparation of the alcohol 95# used in the H&E stain. During an interview on 04/18/2023 at 12:00 PM, the Mohs technician confirmed that the procedure manual failed to include the procedure for preparation of the alcohol 95% used in the H&E stain.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Supervisor (TS) failed to evaluate the annual competency for three testing personnel (TP) during 2022. Findings included: -Review of policy "Training and Competency Procedure" revealed that all TP performing High Complexity testing is required to have an annual competency evaluation signed by the Laboratory Director/Technical Supervisor. -Review of the FORM CMS-209 signed by the Laboratory Director (LD) on 04/04 /2023 revealed that the LD was also the Clinical Consultant (CC), TS and General Supervisor (GS). Listed also that the laboratory had three TP (TP#1, TP#2 and TP#3). -Review of personnel records revealed that all competencies for 2022 were performed by a pathologist that was not listed in the FORM CMS-209 as Director or TS. During an interview on 04/18/2023 at 11:30 AM with the Mohs Technician, he confirmed that the TS failed to perform the competencies listed above.